IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BECTON, DICKINSON AND COMPANY and CELLULAR RESEARCH, INC. Plaintiffs, v. 10X GENOMICS, INC. Defendant.	C.A. No. 1:18-cv-01800-RGA **JURY TRIAL DEMANDED**

DEFENDANT 10X GENOMICS'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(6)

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I. INTRODUCTION

Of the 11 patents asserted by Becton, Dickinson and Company in this case, the 7 patents in the "Fodor" family are directed to the abstract (and patent-ineligible) idea of using different labels to identify different objects. They each claim, in various forms, the abstract idea of labeling different nucleic acid molecules (like DNA) with different labels. Because this amounts to nothing more than an attempt to limit the application of the abstract idea to a particular technological environment (DNA and nucleic acids), the Fodor patents are directed to an ineligible abstract idea under *Mayo* step 1. The Fodor patents also admit in their specification that the other claimed elements (well-known laboratory techniques like attaching labels to DNA, amplifying DNA, detecting DNA, and sequencing DNA) were routine and conventional at the time of the patents in 2009-2010. The claims thus fail to add "significantly more" to the abstract idea and so the Fodor patents are invalid under 35 U.S.C. § 101, *Mayo*, and *Alice*.

The Complaint also discusses certain 10X products that are not addressed or included in any of the alleged counts of infringement. *Compare* D.I. 1, ¶¶ 67-84 (discussing 10X's ATAC and CNV products) *with* ¶¶ 88-223 (failing to even discuss or plead infringement by these products). Because the pleadings are insufficient—indeed, non-existent—as to these products, the portions regarding the ATAC and CNV products should be dismissed (and/or struck).

II. NATURE AND STAGE OF THE PROCEEDINGS

On November 15, 2018, Plaintiffs Becton, Dickinson and Company and Cellular Research, Inc. (collectively, "BD") filed this patent infringement complaint against Defendant 10X Genomics, Inc. ("10X") (D.I. 1) ("Complaint"). The Complaint asserts that 10X is infringing 11 patents, grouped by BD in its Complaint into two families: the 7 "Fodor patents" (U.S. Patent Nos. 8,835,358 ("the 358 patent"); 9,845,502; 9,315,857; 9,816,137; 9,708,659; 9,290,808; and 9,290,809; included as **Exhibits 1-7** to the Complaint, D.I. 1-1) and the 4 "Fan patents" (U.S.

Patent Nos. 9,567,645; 9,567,646; 9,598,736; and 9,637,799; included as **Exhibits 8-11** to the Complaint, D.I. 1-1, 1-2). D.I. 1, ¶¶ 2, 85-313. On December 6, 2018, this Court entered an order extending 10X's time to respond to the Complaint until January 18, 2019. 10X has filed a motion under Federal Rule of Civil Procedure 12(b)(6) to dismiss the Complaint for failure to state a claim upon which relief can be granted and respectfully submits this opening brief in support of that motion.

III. SUMMARY OF THE ARGUMENT

1. *Ariosa* and *Mayo* require finding the Asserted Patents ineligible under 35 U.S.C. § 101 because (under *Mayo* step 1) their claims are directed to the abstract idea of using different labels to label or identify different objects, and (under *Mayo* step 2) the claims add no more than routine, known techniques for working with DNA (such as "amplifying", "detecting", and "sequencing") that the specification admits were well-known by the time of these patents. That is insufficient to transform the claims into "significantly more" than the abstract idea.

2. The Complaint also fails to allege, let alone plead factual support for, infringement of any of the Asserted Patents by 10X's ATAC or CNV products and so BD's Complaint should be dismissed as to those products under *Iqbal* and *Twombly*.

IV. STATEMENT OF FACTS

BD alleges in counts 1-7 that 10X infringes "at least" one (and only one) claim from each of the 7 Fodor patents: 358 patent claim 6, 502 patent claim 1; 857 patent claim 1; 137 patent claim 1; 659 patent claim 1; 808 patent claim 1; and 809 patent claim 1. D.I. 1, ¶¶ 88-90, 107-109, 129-131, 154-156, 167-169, 187-189, and 205-207. Although BD alleges that 10X infringes "at least" these seven independent claims, its pleadings do not even address (let alone plead facts supporting) infringement of any other claims of the Fodor patents. *Id*., ¶¶ 88-223. These Fodor patents are the subject of 10X's § 101 ineligibility arguments, while the arguments regarding insufficient pleading

of the ATAC & CNV products apply to all of the Asserted Patents.

The 358 patent was filed December 15, 2010 and on identifies a provisional application dated December 15, 2009. D.I. 1 Ex. 1 ("358 patent") at 1. The 6 other Fodor patents each state that they are continuations or continuations-in-part dating back to that same December 15, 2010 application and also identify the same provisional application. D.I. 1 Ex. 2 ("857 patent") at 1; Ex. 3 ("137 patent") at 1; Ex. 4 ("809 patent") at 1; Ex. 5 ("808 patent") at 1; Ex. 6 ("659 patent") at 1; and Ex. 7 ("502 patent") at 1. Neither BD's Complaint nor the Fodor patents' specifications assert that attaching, amplifying, detecting, sequencing, or other claimed elements were novel or otherwise not conventional in December of 2009. *See generally*, D.I. 1 Exs. 1-7.

V. LEGAL STANDARD

A. Invalidity Under 35 U.S.C. § 101

The Supreme Court's decision in *Alice* reaffirmed the two-step framework first outlined in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), used to "distinguish[] patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014). In assessing whether a patent claim is ineligible, the Court must determine (1) if the claim is directed to ineligible subject matter such as a natural phenomenon, and if so, (2) whether there are sufficient inventive elements such that the invention is "significantly more" than an ineligible concept. *Id.*

The Supreme Court made clear that "the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of [the idea] to a particular technological environment." *Alice*, 134 S. Ct. at 2355, 2358. Further, the Federal Circuit confirmed that where claims are directed to ineligible subject matter (even if the ineligible subject matter is innovative or groundbreaking), merely "appending routine, conventional steps to a [the ineligible subject

matter], specified at a high level of generality, is not enough to supply an inventive concept." *See Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1377-78 (Fed. Cir. 2015).

Patentability under 35 U.S.C. § 101 is a threshold legal issue. *Bilski v. Kappos*, 561 U.S. 593, 602 (2010). Accordingly, the § 101 inquiry is properly raised at the pleadings stage if it is apparent from the face of the patent that the asserted claims are not directed to eligible subject matter. *See Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018) ("Patent eligibility has in many cases been resolved on motions to dismiss"); *Cleveland Clinic Found v. True Health Diagnostics LLC*, 859 F.3d 1352, 1360 (Fed. Cir. 2017), cert. denied, 138 S. Ct. 2621 (2018). In those situations, claim construction is not required to conduct a § 101 analysis. *Genetic Techs. Ltd v. Merial LLC.*, 818 F.3d 1369, 1374 (Fed. Cir. 2016). A court need not individually address claims not asserted or identified by the non-moving party if the court identifies a representative claim and "all the claims are substantially similar and linked to the same abstract idea." *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat. Ass'n*, 776 F.3d 1343, 1359 (Fed. Cir. 2014). This Court has repeatedly granted motions to dismiss based on § 101. *See, e.g.*, *Tangelo IP v. Tupperware Brands Corp.*, No. 18-cv-692-RGA, 2018 WL 6168083 (D. Del. Nov. 26, 2018); *Finnavations LLC v. Payoneer, Inc.*, No. 18-444-RGA, 2018 WL 6168618 (D. Del. Nov. 26, 2018); *Broadsoft, Inc. v. Callwave Commc'ns, LLC*, 282 F. Supp. 3d 771 (D. Del. 2017); *Callwave Commc'ns LLC v. AT&T Mobility LLC*, 207 F. Supp. 3d 405 (D. Del. 2016).

B. Pleading Standards Under *Iqbal* And *Twombly*

"[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). This "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Factual allegations must be enough to raise a right to relief above the speculative

level." *Twombly*, 550 U.S. at 555.

VI. ARGUMENT

A. The Claims Of The Fodor Patents Are Invalid Under § 101.

1. The Claims Of The Fodor Patents Are Directed To The Abstract Idea Of Labeling Different Objects With Different Labels.

The claims of the Fodor patents are directed to the abstract idea of labeling different objects with different labels. This concept is as old as the scientific method and is familiar to every student in any introductory science class—when performing an experiment, one needs a control and an experiment and will label them accordingly (whether that means written labels of "control" and "experiment" or "test 1" and "test 2" or "sample A" and "sample B" or even some other form of labeling such as placing one in a green cup and one in a blue cup). Even outside of the context of scientific experiments, using different labels to differentiate and distinguish between different instances of similar objects is commonplace. For example, different instances of the same model of a television set are given different serial numbers for warrantee or recall purposes; people attending a convention are given different name tags; and different books in a library are given different classification numbers (under the Dewey Decimal System) and are assigned different International Standard Book Numbers (ISBNs) (by the Library of Congress). The Fodor patents did not invent this idea—they simply take this abstract idea and attempt to limit the use of the idea to the particular technological environment of DNA (and other nucleic acids) by adding "attaching", "amplifying", "detecting" steps and other similarly generic techniques that were well-known and conventional before 2009 (the earliest provisional application). The claim language and intrinsic record confirm this, and no assertions in the Complaint dispute it.

Claim 6 of the 358 patent and claim 1 of each of the other Fodor patents are the only claims of the Fodor patents addressed in the Complaint. D.I. 1, ¶¶ 88-90, 107-109, 129-131, 154-156, 167-169, 187-189, and 205-207. For four of the Fodor patents, the claim addressed in the

Complaint is the sole independent claim (*see* 857, 137, 808, and 502 patents) while the 358, 809, and 659 patents each contain a second independent claim that is not addressed by the Complaint (*see* 358 patent claim 1, 809 patent at claim 14, and 659 patent claim 13).

Claim 6 of the 358 patent is nakedly directed at the abstract idea of labeling different objects (two or more "nucleic acid molecules", e.g., portions of DNA) with different labels ("a plurality of nucleic acid label-tags with different sequences"). 358 patent at claim 6. Specifically, it claims a method that comprises a step (a) of combining "at least two distinct target nucleic acid molecules" (the different objects) "with a pool of nucleic acid label-tags" where "a plurality of [the] nucleic acid label tags" have "different sequences" (the different labels). *Id*. It then requires an "attaching" step (b) of "attaching at least two nucleic acid label-tags from the pool . . . to the at least two distinct target nucleic acid molecules"; an "amplifying" step (c) described generically without any specifics regarding what amplification technique is to be used; and then a "detecting" step (d) also described generically without any specific or concrete requirements:

358 patent Claim 6	Summary
6. A method comprising:	Preamble
(a) combining a mixture comprising at least two distinct target nucleic acid molecules with a pool of nucleic acid label-tags, wherein the pool of nucleic acid label-tags comprises a plurality of nucleic acid label-tags with different sequences;	Different molecules ("two distinct target nucleic acid molecules") and Different labels ("a pool of nucleic acid label-tags")
(b) attaching at least two nucleic acid label-tags from the pool of nucleic acid label-tags to the at least two distinct target nucleic acid molecules to obtain at least two label-tag-target nucleic acid molecules, wherein the distinct target nucleic acid molecules have different sequences from one another;	Generic, conventional attaching techniques
(c) amplifying at least a portion of the label-tag-target nucleic acid molecules, wherein an amplified portion of the label-tag-target nucleic acid molecules comprises at least a portion of said target nucleic acid molecule; and	Generic, conventional amplifying techniques
(d) detecting an amplified product of step (c).	Generic, conventional detecting techniques

Id. Though the claim does include "nucleic acid molecules" and "nucleic acid label-tags", these

elements do nothing more than attempt to limit the application of the abstract idea (using different labels to label or identify different objects) to the particular technological environment of DNA biochemistry.

For purposes of this Motion and the *Mayo* analysis, claim 6 of the 358 patent is representative of each of the other claims of the Fodor patents addressed in counts 1-7 of BD's Complaint. As addressed further in the analysis of *Mayo* Step 2 below, the other independent claims of the Fodor patents (like the dependent claims that are not addressed in BD's Complaint) add (at most) only conventional, routine elements to the same abstract idea.

Like 358 patent claim 6, claim 1 of the 857, 137, 808, and 502 patents are method claims directed to the same abstract idea of labeling different objects with different labels. *See* 857 patent at claim 1 ("attaching ***a plurality of diverse label-tags to a nucleic acid target*** . . . thereby producing a plurality of labeled targets" and then "amplifying" and "detecting" the "labeled targets" to "determin[e] the number of copies of the nucleic acid target");[1] 137 patent at claim 1 ("***attaching*** a plurality of primers ***to the plurality of nucleic acids*** from the sample, wherein each primer . . . comprises ***a different variable label region***") and at claim 10 (adding "amplifying" and "detecting" steps); 808 patent at claim 1 ("***combining*** in a specified container a sample comprising ***a plurality of target molecules*** from a single cell ***with a plurality of diverse label-tag*** [sic]", "generating a plurality of target-label-tag-molecules", "amplifying the target-label-tag molecules", and "sequencing at least a portion of the amplified product"), and 502 patent at claim 1 ("***combining each of a target molecule*** from a plurality of target molecules from a single cell ***with a label-tag***", "hybridizing the label-tag of the plurality of diverse label-tags to the target molecule", "amplifying the plurality of target-label-tag molecules", and "sequencing at least a portion of the plurality of amplified products").

[1] Emphasis is supplied, and internal citations are omitted throughout unless otherwise noted.

Similarly, although claim 1 of the 809 and 659 patents are "composition" and "system" claims (respectively), they are also directed to the same abstract idea. *See* 809 patent at claim 1 ("a composition comprising ***a plurality of oligonucleotide labels*** . . .") and claim 2 ("The composition of claim 1, further comprising a set of n target molecules hybridized to said plurality of oligonucleotide labels."); 659 patent at claim 1 ("a system for counting n, wherein n is a number of nucleic acid target molecules . . . comprising:" "a) a diverse set of labels . . .", "b) a plurality of reaction vessels for attaching a label from the diverse set of labels to each occurrence of the nucleic acid target molecules . . .", and "c) processing software for counting n from a number of labeled nucleic acid target molecules detected."). Like claim 6 of the 358 patent (and the method claims of the other asserted Fodor patents), these claims amount to nothing more than the abstract idea of using different labels to label different objects combined with generic, well-known, routine laboratory techniques. The claims do not include any limitations directed at improving the well-known techniques of attaching, amplifying, detecting, or sequencing DNA apart from adding the abstract idea of using different labels to label different DNA molecules.

The specification of the Fodor patents[2] confirms that this abstract idea—using different labels for different molecules—is the (purportedly) inventive aspect of the claims. The patents are titled "Digital Counting Of Individual Molecules By Stochastic Attachment Of Diverse Labels"—i.e., counting of molecules by attaching different labels to them. D.I. 1-1 (Exs. 1-7). The Abstract similarly focuses on this same abstract labeling idea:

> Compositions, methods and kits are disclosed for high-sensitivity single molecule digital counting by the stochastic ***labeling of a collection of identical molecules by attachment of a diverse set of labels***. . . . This stochastic transformation relaxes the problem of counting molecules from one of locating and identifying identical

[2] Because each of the other asserted Fodor patents is a continuation or continuation-in-part of the 358 patent application, citations throughout are to the 358 patent's specification. Unless otherwise noted, the same or similar disclosures are present in each of the other asserted Fodor patents (although the 857 patent frequently replaces the word "label(s)" with "label-tag(s)").

> molecules to a series of binary digital questions ***detecting whether preprogrammed labels are present***.

358 patent at Abstract.[3] As does the "Field of the Invention" section: "Methods, compositions and products for counting individual molecules by stochastic ***attachment of diverse labels from a set of labels***, followed by amplification and detection are disclosed." *Id*. at 1:11-17.

The "Background of the Invention" section acknowledges the existence of many known, conventional techniques already "developed to measure the relative abundance of different molecules" (*id*. at 2:45-47) such as: "microarrays and sequencing" (*id*. at 2:47); "PCR" and "digital PCR" (*id*. at 2:53-3:25); and various "hybridization-based techniques" (including "Both digital and non-digital hybridization based assays") (*id*. at 1:32-2:34). The background section identifies two purported shortcomings of the prior art: that "few techniques are available to determine the absolute number of molecules in a sample" and that "Methods for estimating the abundance or relative abundance of genetic material having increased accuracy of counting would be beneficial." *Id*. at 2:47-49 and 1:29-31.

However, the Summary of the Invention section confirms that any purported benefit from the claimed inventions of the Fodor patents come only from the abstract idea of labeling different molecules with different labels:

> High-sensitivity single molecule digital counting by the stochastic labeling of a collection of identical molecules is disclosed. . . .
>
> Methods are disclosed herein for digital counting of individual molecules of one or more targets. In preferred embodiments the targets are nucleic acids, but may be a variety of biological or non-biological elements. ***Targets are labeled so that individual occurrences of the same target are marked by attachment of a different label*** to difference [sic] occurrences. . . . Preferably the labels are different sequences that tag or mark each target occurrence uniquely.

Id. at 3:26-31, 3:55-64[4]. Indeed, the Summary of the Invention is devoid of any discussion at all

[3] The Abstract of the 857 patent contains slightly different language but is substantively the same. *See* 857 patent at Abstract.
[4] The 857 patent again contains substantively the same disclosure. *See* 857 patent at 4:21-33.

of the other various (known, conventional) laboratory techniques that appear in the claims (let alone any specifics about ***how*** to attach, hybridize, amplify, detect, or sequence nucleic acid molecules, or even how to form or deliver the labels). *See id*. at 3:26-4:26.

The Figures and Detailed Description of the Invention similarly confirm that the purported invention of the Fodor patents amounts to nothing more than the abstract idea of labeling different molecules with different labels, combined with known, conventional techniques like amplification, detection, and microarrays:

> Methods for performing single molecule digital counting by the stochastic labeling of a collection of identical molecules are disclosed. As illustrated in FIGS. 1, 2A and 2B, ***each copy of a molecule*** (from a collection of identical target molecules 103) randomly ***captures a label*** by choosing from a large, non-depleting reservoir of diverse labels 101. . . . ***Once the molecules are labeled each has been given a unique identity and can now be separately detected***.

Id. at 17:66-18:9; *id*. at Fig. 2A[5] (depicting the pool of different labels ($l_{1...960}$) for attaching to 4 copies of the target molecule (t_1-t_4) which are then amplified and detected using known, conventional techniques); *see also*, *id*. at Figs. 1-2B and 18:32-19:12 (describing Figs 1-2B).

The prosecution history, part of the intrinsic record, confirms that the abstract idea of labeling different molecules with different labels was the purportedly novel aspect necessary for the claims to issue over the prior art. In response to an obviousness rejection, the applicant had an interview with the examiner and convinced the examiner that the prior art reference "does not teach attaching label-tags to two distinct target nucleic acid molecules as claimed in [claim 6]." **Ex. A** (March 4, 2014 Applicant Response) at 11; [6] *see also* **Ex. B** (Oct. 3, 2013 non-final rejection); **Ex. C** (interview summary); and **Ex. D** (Notice of Allowance). The other elements alone (attaching, amplifying, and detecting) were not sufficient to lead to allowance.

As this Court has found, claims that "describe concepts 'long-practiced in our society' have

[5] In the 857 patent, this same figure is Figure 1 instead of Figure 2A.
[6] What issued as claim 6 of the 358 patent was claim 39 at the time of the applicant response.

been found directed to an abstract idea under *Alice* step one." *Tangelo IP, LLC v. Tupperware Brands Corp.*, No. 18-692-RGA, 2018 WL 6168083, *6 (D. Del. Nov. 26, 2018) (citing *Intellectual Ventures I LLC v. Capital One Bank (USA)*, 792 F.3d 1363, 1369-70 (Fed. Cir. 2015); *Content Extraction & Transmission LLC v. Wells Fargo Bank*, 776 F.3d 1343, 1347 (Fed. Cir. 2014)); *see also LendingTree, LLC v. Zillow, Inc.*, 656 F. App'x 991, 996-97 (Fed. Cir. 2016) ("the concept of applying for loans and receiving offers is also long prevalent in our financial system" and performing that method on the Internet did not redeem the abstractness of the claimed idea); *In-Depth Test, LLC v. Maxim Integrated Products, Inc. et al.*, No. 14-887-CFC 2018 WL 6617142, at *5 (D. Del. Dec. 18, 2018) (finding the step of "identifying" data "that fall[s] within control limits" to be "essentially 'doing math'" and thus an abstract idea because it is "akin to calculating standard deviations."); *Guada Techs. LLC v. Vice Media, LLC*, No. 17-1503-RGA, 2018 WL 4441460, at *7-8 (D. Del. Sept. 17, 2018) (finding the steps of "'receiving an input,' 'identifying at least one node,' and "jumping [to the next node]" to be "steps that a person can perform mentally in navigating a decisional hierarchy" and the subject patent "provides no information as to how they might improve the functionality of a computer or computerized data set."); *Intellectual Ventures I LLC v. AT&T Mobility II LLC*, 235 F. Supp. 3d 577, 594 (D. Del. Dec. 30, 2016) (Stark, J.) (finding steps of "receiving, analyzing, and making a decision as to whether to forward a message based on set criteria" abstract because they "could be analogously performed by a human, instead of by a computer"); *Idexx Labs., Inc. v. Charles River Labs.*, No. 15-668-RGA, 2016 WL 3647971, at *4 (D. Del. Jul. 1, 2016) (claims directed to "the abstract idea of collecting, analyzing, and reporting results"); *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1354 (Fed. Cir. 2016) ("process of gathering and analyzing information of a specified content" is an abstract idea).

In *Tangelo*, this Court granted the defendant's motion to dismiss based on § 101 ineligibility, finding that the claims were directed to a long practiced abstract idea applied in a

particular technological environment (there, a generic computer) without any added inventive concept to render them patent-eligible:

> Rather, I believe the '005 patent claims are directed to the abstract idea of using an identifier to allow a reader of a printed publication to access related information not in the printed publication—the same concept long practiced by systems of sales representatives and printed product catalogs. . . .
>
> The '005 patent claims do not have an inventive concept that renders them patent eligible. Claim 1 merely applies the abstract idea of using a catalog identifier to obtain additional product information in a generic computer environment.

Tangelo, 2018 WL 6168083 at *4.

The claims of the Fodor patents similarly fail under *Mayo/Alice* step 1 because they are directed to the long-practiced idea of labeling different instances of an object with different labels applied in the particular technological environment of DNA and other nucleic acid molecules. Merely applying this "old solution" of different labels in the particular technological environment of DNA is insufficient to produce patent-eligible claims. *Alice*, 134 S. Ct. at 2358 ("the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of [the idea] to a particular technological environment"); *Intellectual Ventures I LLC v. Erie Indem. Co.*, 850 F.3d 1315, 1330 (Fed. Cir. 2017) ("An abstract idea does not become nonabstract by limiting the invention to a particular field of use or technological environment, such as the Internet.'"); *Finnavations*, 2018 WL 6168618 at *4-5 (granting motion to dismiss, finding "the claims here merely apply an 'old solution' (bookkeeping) in a computer environment without specifying any non-conventional way to accomplish or practice the idea.").

Here, like this and other Courts found in *Tangelo*, *Finnavations*, *Intellectual Ventures I*, *Content Extraction*, and many similar cases, humans have long performed the abstract idea of using different labels to label or identify different instances of an object, including using serial numbers to distinguish between particular television sets, Dewey Decimal card catalogue numbers to distinguish between books in the library, labels on test tubes to distinguish between samples in

an experiment, or even name tags to distinguish between attendees at a convention or meeting. Attempting to limit the application of that abstract idea to DNA (and other nucleic acid molecules) does not save the claims of the Fodor patents under *Mayo* step 1 any more than would limiting the application of the abstract idea to the Internet or to a generic computer. The Fodor patents are thus directed at ineligible subject matter under *Mayo* step 1.

2. The Claims Of The Fodor Patents Add Only Routine, Conventional DNA Laboratory Techniques To The Abstract Idea.

Because the asserted claims of the Fodor patents are directed to an abstract idea under Step 1, they can satisfy § 101 only if they can survive *Mayo* Step 2 by reciting sufficient additional inventive elements such that the invention is "significantly more" than the ineligible abstract idea. *Alice*, 134 S. Ct. at 2357. They cannot, because they do not recite ***any*** additional inventive elements. Instead, the claims recite only the abstract labeling idea together with generic, routine, well-known laboratory techniques for working with DNA and other nucleic acid molecules (like attaching, hybridizing, amplifying, detecting, and sequencing). The specification repeatedly admits that these techniques were known and conventional before the Fodor patents.

In contrast to the many discussions in the specification of the importance of labeling different molecules with different labels (the abstract idea already addressed above), the specification describes the other elements of the asserted claims of the Fodor patents as routine and conventional. Indeed, in addition to the many known techniques described in the Background to the Invention (358 patent at 1:18-3:25), even the "Detailed Description of the Invention" begins by explaining that "[t]he invention has many preferred embodiments ***and relies on many patents, applications and other references for details known to those of the art***" (*id*. at 5:63-65) and then spends the next six columns describing numerous known, routine laboratory techniques and citing a host of prior art patents, articles, and laboratory manuals (*id*. at 5:65-11:22, 12:40-13:8).

Claim 6 of the 358 patent adds "attaching", "amplifying", and "detecting" steps to the

abstract idea of labeling different molecules with different labels. *Id*. at claim 6. Each of these are expressly admitted to be known, routine laboratory techniques. In fact, the specification admits that tags (i.e., labels) have previously been used in combination even with "next-generation sequencing methods"—a procedure that requires attaching the tags, amplifying the DNA, and then sequencing (and thus detecting) the DNA. *Id*. at 2:31-34 ("Tagging approaches have also been used in combination with next-generation sequencing methods."); *see also id*. at 23:43-46 ("The label-tag sequences are not target specific, but are like the tags that have been used for other tagging applications, for example, the Affymetrix GENFLEX tag array"); 33:7-11 ("Many of the examples provided herein identify the label based on unique nucleic acid sequence but any distinguishable label may be used . . .").

The "attaching" step is repeatedly described as being accomplished through "ligation", a technique the Fodor patents admit was known. *Id*. at 24:4-6 ("The label-tag may be attached to the target by any method available. In one embodiment, the label-tag is attached by ligation of the label-tag to one of the ends of the target.");[7] 9:7-30 (stating that "Methods of ligation will be known to those of skill in the art and are described, for example in Sambrook et at. [sic] (2001) and the New England BioLabs catalog both of which are incorporated herein by reference" and then listing many known ligation methods for attaching labels and label tags to DNA); *see also*, *id*. at 24:20-29 and 24:52-54 (further describing known ligation methods).

"Amplifying" DNA and other nucleic acid molecules is similarly described as known and the specification lists numerous example conventional amplification techniques. E.g., *Id*. at 8:6-25 (stating that "Prior to or concurrent with analysis, the genomic sample may be amplified by a variety of mechanisms, some of which may employ PCR" and then citing and incorporating by reference multiple articles from the 1990s regarding PCR amplification); 7:13-34 (similar); 8:26-

[7] The 857 patent deletes the first of these two sentences. *See* 857 patent at 30:51-52.

46 (identifying and citing prior art references describing "Other suitable amplification methods" including "ligase chain reaction (LCR)", "transcription amplification", "self-sustained sequence replication", "arbitrarily primed polymerase chain reaction (AP-PCR)", "rolling circle amplification (RCA)", and others); and 8:56-9:6 (explaining that "amplification may include the use of strand displacing polymerase" and identifying additional articles further describing that).

Multiple routine, conventional "detecting" techniques are similarly admitted. *Id*. at 32:27-28 ("Any available mechanism for detection of the labels may be used."); 6:25-47 ("The practice of the present invention may employ, unless otherwise indicated, conventional techniques . . . ***Such conventional techniques include*** polymer array synthesis, hybridization, ligation, and ***detection of hybridization using a label***.""); 2:15-34 (admitting that even detection of labeled or tagged nucleic acid molecules was known, explaining that "[b]oth digital and non-digital hybridization-based assays have been implemented using oligonucleotide tags that are hybridized to their complements, typically as part of a detection or signal generation schemes . . ." and identifying prior art articles about that dating back to 1988); 20:46-49 ("Digital PCR is an absolute counting method where solutions are stochastically partitioned into multi-well containers until there is an average probability of one molecule per two containers, then detected by PCR."); 3:16-21 and 12:40-13:5 (further describing digital PCR as a method of detecting and citing prior art articles about it); 2:45-47 ("many analytical methods have been developed to measure the relative abundance of different molecules through sampling (e.g., microarrays and sequencing)"); *see also* 1:37-44; 2:53-56; 32:53-33:3 (further disclosing known "detecting" techniques).

The other claims of the Fodor patents fare no better and similarly add (at most) only generic, routine, conventional elements that are insufficient to render the claims "significantly more" more than the abstract labeling idea itself. For example, beyond the steps already addressed for claim 6 of the 358 patent, claim 1 of the 857 patent claims the "label-tag" "comprises

nucleotides selected from purine bases, pyrimidine bases, natural nucleotide bases" or a variety of other base types, but the specification again admits that such tags were known and conventional. 358 patent at 2:15-26 ("Both digital and non-digital hybridization-based assays have been implemented using oligonucleotide tags" and citing articles back to 1988); 14:5-47 (describing "oligonucleotide" and "nucleic acid" as being made of the same base types listed in 857 patent claim 1).

Claim 1 of the 808 and 502 patents additionally claim "sequencing" steps. The Fodor patents similarly admit that sequencing (including next-generation sequencing) was known and conventional. 358 patent at 2:31-34 ("Tagging approaches have also been used in combination with next-generation sequencing methods."); 2:45-47 ("many analytical methods have been developed to measure the relative abundance of different molecules through sampling (e.g., microarrays and sequencing)"); 20:31-33 ("Microarray and sequencing technologies are commonly used to obtain relative abundance of multiple targets in a sample."); 13:1-5 (Explaining how Digital PCR has been used to quantify sequencing libraries.)

Claim 1 of the 137 patent additionally claims attaching and extending "primers" to produce double-stranded labeled nucleic acids; however, the specification admits such "hybridization" techniques, as well as PCR that involves binding and extending primers, were known and were used with label tags. 358 patent at 13:23-51 (describing "hybridization" as known and as "the process in which two single-stranded polynucleotides bind . . . to form a stable double-stranded polynucleotide"); 2:15-29 and 2:53-56 (describing "hybridization-based assays" and "PCR, hybridization" as known and as having "been implemented using oligonucleotide tags that are hybridized to their complements.").

Claim 1 of the 809 patent claims, apart from the abstract idea of labels, "an oligo dT sequence" and "a sequencing primer binding site" but again the Fodor patents admit that primer

binding including the use of oligo dT was known and conventional. 358 Patent at 24:47-54 (describing known ligation techniques including use of oligo dT priming and citing a 1992 article); *see also id*. at 24:4-46 (further describing known ligation techniques and identifying prior art dating back to 1983).

Claim 1 of the 808 patent, claim 1 of the 502 patent, and claim 1 of the 659 patent each claim that "the ratio of the number of diverse label-tag sequences to the number of occurrences of a target molecule is greater than 5." 808 patent at claim 1; *see also* 502 patent at claim 1 and 659 patent at claim 1 (each containing similar language regarding a ratio of labels to molecules greater than 5). However, the specification confirms that this ratio selection is just performing math (358 patent at 19:54-20:7), and is thus itself an unpatentable, ineligible abstract idea that cannot save these claims. *See In-Depth Test*, 2018 WL 6617142, at *5 (finding the step of "identifying" data "that fall[s] within control limits" to be "essentially 'doing math'" and thus an abstract idea because it is "akin to calculating standard deviations."); *see also Parker v. Flook*, 437 U.S. 584, 594-595 (1978) (finding unpatentable formula for calculating alarm limits during the catalytic conversion of hydrocarbons); *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972) (finding that "[t]he mathematical formula involved here has no substantial practical application except in connection with a digital computer, which means that if the judgment below is affirmed, the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself"); *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1168 (Fed. Cir. 2018) (finding claims abstract because "the focus of the claims is not a physical-realm improvement but an improvement in wholly abstract ideas—the selection and mathematical analysis of information"); *Digitech Image Techs., LLC v. Electronics for Imaging, Inc.*, 758 F.3d 1344, 1351 (Fed. Cir. 2014) (finding abstract "a process of taking two data sets and combining them into a single data set" because it "employs mathematical algorithms to manipulate existing information to generate

additional information.")

Claim 6 of the 659 patent additionally claims "reaction vessels" and "processing software", but again these generic limitations cannot save the claim under *Mayo* step 2 and are admitted to be conventional and routine by the specification. 358 patent at 9:51-10:8 (describing multiple known computer implemented methods and identifying prior art regarding counting and working with nucleic acid data); 10:52-11:22 (further describing and identifying "conventional biology methods, software and systems" including "computer program products and software for a variety of purposes, such as probe design, management of data, analysis, and instrument operation" and "Computer methods related to genotyping using high density microarray analysis" and identifying prior art regarding the same); 6:48-7:12 (describing a wide variety of known prior art reaction vessels, including solid substrates and nucleic acid arrays).

The Complaint does not contend that any of the elements of the Fodor patent claims were unconventional at the time of the Fodor patents. D.I. 1. Thus, even accepting all reasonable assertions in the Complaint, the Fodor patents, and the intrinsic record as true, there is no evidence that these elements add anything to the natural phenomenon other than conventional, routine steps. *Cf. Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018) ("Patent eligibility has in many cases been resolved on motions to dismiss"); *see also, e.g.*, *TriPlay, Inc. v. WhatsApp Inc.*, No. 13-1703-LPS-CJB, 2018 WL1479027, at *10 (D. Del. Mar. 27, 2018) (claims failed Step Two of *Alice* because "[n]either the claims nor the specification explain what is inventive about [] the identifier, alone or in combination with other steps of the claims.").

Ariosa and *Mayo* require finding these Fodor patents ineligible. Mere addition of conventional, routine techniques is insufficient to render the claims "significantly more" than the ineligible abstract idea under *Mayo* Step 2. In *Mayo*, the added elements of administering the drug treatment and determining the metabolite levels were known, conventional steps that were

insufficient to save the claims. *Mayo*, 132 S. Ct. at 1296-97. Likewise, in *Ariosa*, the added elements of amplifying and determining the presence of a particular amino acid were "known laboratory techniques" insufficient to save the claims (even where the ineligible subject matter was itself considered a groundbreaking discovery made by the inventors). *Ariosa*, 788 F.3d 1373-74. Judge Illston recently applied *Ariosa* and found invalid patents that, like the Fodor patents, add only routine, conventional steps to ineligible subject matter. *Illumina, Inv. v. Ariosa Diagnostics, Inc.*, No. 18-cv-02847-SI, 2018 WL 6735143 at *6-8 (N.D. Cal. Dec. 24, 2018).

As in the cases of this Court addressed in the discussion of *Mayo* step 1 above (and as in *Ariosa* and *Mayo*), the Fodor patent claims fail to add "significantly more" to the ineligible abstract idea of labeling. Instead, they merely add conventional, routine laboratory techniques in an attempt to limit the use of the abstract idea to the particular technological environment of DNA and nucleic acids. The Fodor patents are thus invalid under § 101, *Alice*, and *Mayo*.

B. BD Fails To Plead A Claim For Relief As To 10X's ATAC & CNV Products.

Before turning to the alleged counts of infringement, the Complaint discusses 10X's ATAC and CNV product lines. D.I. 1, ¶¶ 67-84. However, the Complaint expressly limits the defined term "Accused Products" to 10X's "Single Cell 3' Workflow Accused Products" and "Single Cell 5' Workflow Accused Products"—themselves defined terms that do not include either the ATAC or CNV product lines. *Id*., ¶ 66 (defining "Accused Products") and ¶¶ 41, 65.

BD's allegations of infringement in each of the counts are similarly limited only to the defined "Accused Products" and the facts that BD pleads as purported support for its infringement allegations (including all of the documents relied on by BD) address only 10X's Single Cell 3' or Single Cell 5' products. *Id*., ¶¶ 88 (alleging 10X infringes by "importing the ***Accused Products*** and/or making, using offering for sale, and selling the ***Accused Products*** . . .") and ¶ 89 (alleging "As demonstrated below, the ***Accused Products*** satisfy the claim limitations of at least claim 6 of

the ’358 patent.”); *see also id.*, ¶¶ 88-223 (other counts and purported supporting facts addressing only Single Cell 3’ or Single Cell 5’ products).

Because BD does not even allege infringement based on the ATAC or CNV product lines—let alone plead sufficient supporting facts under *Iqbal* and *Twombly*—its Complaint should be dismissed as to these products (and/or, the paragraphs regarding these products should be struck under Rule 12(f)). *See, e.g.*, *Sipco, LLP v. Streetline, Inc.*, 230 F. Supp. 3d 351 (D. Del. 2017) (granting motion to dismiss where plaintiff merely identified its asserted patents and identified products sold by defendant); *North Star Innovations, Inc. v. Micron Tech. Inc.*, No. 17-506-LPS-CJB, 2017 WL 5501489 (D. Del. Nov. 16, 2017) (“There needs to be some *facts* alleged that articulate *why it is plausible* that the other party’s product infringes that patent claim—not just the patentee asserting, in conclusory fashion, that it is so.”) (emphasis in original).

VII. CONCLUSION

For the foregoing reasons, 10X respectfully requests that the Court dismiss counts 1-7 of the Complaint in full and dismiss all counts as to 10X’s ATAC and CNV products.

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